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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/900,038

Applicant(s)

MIYAKE ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2001 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 6-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

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DETAILED ACTION

The preliminary amendment filed July 9, 2001 amending claims 9, 14 and 15 and adding claims 20-24 has been entered.

Claims 1-24 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a β -1,3-galactosyltransferase, classified in class 435, subclass 193.
- II. Claims 6-13 and 20-24, drawn to a DNA encoding β -1,3-galactosyltransferase, a vector containing it, a host cell containing thereof, a method of making a polypeptide using a host cell, classified in class 435, subclass 193.
- III. Claims 14-19, drawn to a method of making a galactose-containing carbohydrate, classified in class 435, subclass 74.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because an enzyme and a DNA are different compounds each with its own chemical structure and function, and they have different utilities. A DNA molecule of invention II can be used for the production of an

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enzyme of invention I and as a hybridization probe, for example. An enzyme of invention I can be obtained by a materially different method such as by the biochemical purification and it can be used for the production of an antibody, for example.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced with a biochemically purified or chemically synthesized enzyme and not only with a recombinant cell producing said enzyme. A recombinant cell can be used for producing a galactose-containing carbohydrate of invention III and in a method for producing of the enzyme of invention II.

During a telephone conversation with Mr. Lawrence Perry on July 31, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on January 5, 2001. It is noted, however, that applicant has not filed a certified copy of the Japanese 2001-392 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The instant application contains no IDS.

Drawings

The drawings filed concurrently with the application on July 9, 2001 have been approved by Draftsman.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded

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hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See, for example, page 10.

It appears that description of the drawings given on page 3 is incorrect in that the description of Figure 1 is given as the description of Figure 2 and vice versa. Further, the heading usually reads "Brief description of the Drawings".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a β 1,3-galactosyltransferase from *any* microorganism having activity of transferring galactose to N-acetylglucosamine with β 1,3-linkage. Claim 2 limits the microorganism to *Streptococcus* and claim 3 limits the microorganism to *Streptococcus agalactiae*. There are no structural limitations in the claims.

Thus, the claims recite an enormous genus of β 1,3-galactosyltransferases characterized only by function. The claimed genus encompasses not only the single

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Applicants did not disclose all proteins having the requisite function in *Streptococcus agalactiae*. They did not teach any identifying characteristics in addition to the activity. Said activity is characterized qualitatively by one reaction only. It is likely that the disclosed enzyme is able of transferring galactose to some other acceptors while not able to transferring it to some acceptors such as *N*-acetylgalactosamine, for example. And vice versa other galactosyltransferases from *Streptococcus agalactiae* are likely to transfer galactose to *N*-acetylglucosamine with β 1,3-linkage to a certain degree.

The specification discloses only a single species of the claimed genus, a β 1,3-galactosyltransferase from *S. agalactiae* having activity of transferring galactose to *N*-acetylglucosamine with β 1,3-linkage and having the sequence of SEQ ID NO:1.

The specification fails to describe any other representative species by any identifying characteristics or properties other than the “functionality” of being β 1,3-galactosyltransferase having activity of transferring galactose to *N*-acetylglucosamine with β 1,3-linkage and fails to provide any structure: function correlation present in all members of the claimed genus.

Further, with regard to the claimed genus of β 1,3-galactosyltransferases having activity of transferring galactose to *N*-acetylglucosamine with β 1,3-linkage, the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the

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genus from other proteins such that one can visualize or recognize the identity of the members of the genus.

Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a β 1,3-galactosyltransferase having activity of transferring galactose to N-acetylglucosamine with β 1,3-linkage and having the sequence of SEQ ID NO: 1, does not reasonably provide enablement for any β 1,3-galactosyltransferase having activity of transferring galactose to N-acetylglucosamine with β 1,3-linkage and having unknown structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Claims 1-3 are so broad as to encompass any β 1,3-galactosyltransferase with unknown possible low homology to the β 1,3-galactosyltransferase from *S. agalactiae*. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of β 1,3-galactosyltransferases broadly encompassed by the claims. Since the amino acid sequence of a protein

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determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of a single β 1,3-galactosyltransferase having activity of transferring galactose to N-acetylglucosamine with β 1,3-linkage having the sequence of SEQ ID NO: 1.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims because the specification does not establish: (a) regions of the protein structure which may be modified without effecting the specific β 1,3-galactosyltransferase activity; (B) the

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general tolerance of β 1,3-galactosyltransferase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any a β 1,3-galactosyltransferase residues with an expectation of obtaining the desired enzymatic function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. The specification does not teach what residues are important for the specific β 1,3-galactosyltransferase activity of the claimed enzyme as compared with a β 1,3-galactosyltransferase having different properties and substrate and stereo specificity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a β 1,3-galactosyltransferase having activity of transferring galactose to N-acetylglucosamine with β 1,3-linkage of any structure. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making a β 1,3-galactosyltransferase having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites "amino acids [are] deleted, replaced, inserted or added". The difference between "inserted" and "added" is unclear rendering the metes and bounds of the claim indefinite.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected as drawn to a protein that is naturally-occurring in *Streptococcus agalactiae*. As a product of Nature, it is unpatentable. Amending the claims to recite "an isolated or purified protein" would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

a person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Miyake et al.

Miyake et al. (June 1, 2001) teach CpsJ gene of *Streptococcus agalactiae*. They teach that said gene encodes β -1,3-galactosyltransferase. The sequence of said enzyme is 100% identical to SEQ ID NO:1 of the instant invention.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because said papers and a translation thereof has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner

August 6, 2002